

1. General Information

1.1 Scope of Application

This Manual applies to the following products:

- Navigator Star/ Navigator Star Care

The models differ as follows:

Models	Detector	
	Models	Pixel Size
Navigator Star Care	AXS-2430FDI	85um
Navigator Star	CV-MTC	77um

1.2 Warning Instructions

Warning: Warning is used to indicate that there is a risk of injury or death of the patients, operators or other people.



Warning:

First, indicate the danger source.

Then, indicate the possible consequence.

- ◆ Finally, provide the information about how to avoid the danger.

Caution: "Caution" is used to indicate that slight injury or system damage may occur in case of improper system use.



Caution:

First, indicate the danger source.

Then, indicate the possible consequence.

- ◆ Finally, provide the information about how to avoid the danger.

Note:

It has the following two purposes:

- ◆ Series information emphasizing that safety is related and there is no direct danger.
 - ◆ Summary containing the most important information with regard to a certain subject.
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1.3 Technical Specification

1.3.1 General Information

Power Supply

Input of Power Supply	Single phase, AC 230V~, 50/60Hz
Input Power of Equipment	8500VA
Apparent Impedance of Power Supply	$\leq 0.6\Omega$
Mains fuses input side	30A recommended: Type FLM 30A(slow blow)

Generator

Maximum Output Power	5kW
Voltage of X-Ray Tube	20kV - 40kV, adjustment step size: 1kV
mAs Range	2mAs - 630mAs
kVp Accuracy	$\pm 1\text{kV}$
mAs Accuracy	$\pm 10\% + 0.2\text{mAs}$

Detector

	CV-MTC	AXS-2430	AXS-2430FDi
Pixel Size	77 μm	85 μm	85 μm
Spatial Resolution	7 lp/mm	6 lp/mm	6 lp/mm
DQE	>60%, @1 lp/mm >30%, @5 lp/mm	>50%, @1 lp/mm >20%, @5 lp/mm	>50%, @1 lp/mm >20%, @5 lp/mm
Active Area	23.6cmx31.3cm	24cmx30cm	24cmx30cm
Matrix Size	3072x4096	2816x3584	2816x3584

Automatic Exposure Control

AEC mode applies to the kV range of 20~40kV.


Under the condition of correct clinical kV, anode/filtration material and thickness (20~70mm), the deviation of

repeatability application dose or current time integration of automatic exposure control is $\leq 5\%$.

AEC Exposure Mode The user may select three exposure modes on the interface.

X-Ray Tube

Focus spots size  0.1mm

 0.3mm

Maximum tube assembly heat content 320kJ (416kHu)

Maximum anode heat content 225kJ (300kHu)

Anode material Tungsten Target

Inherent Filtration 0.05mm Be

Anode Speed 3,000rpm/10,000 rpm

Anode angle  10°

 16°

Collimator

Additional filtration Rh:0.05mm, Ag: 0.05mm

X-ray field range The field range is electrically adjusted according to the size of the compression plate, and the maximum field size is consistent with the imaging area of the detector.

System attenuation factor

Material attenuation factor between the upper surface of the breast pallet and the image receiver plane < 2

Object table $< 0.3\text{mmAl}$

Magnification table $< 0.3\text{mmAl}$

Calculated, absorbed glandular dose

The dose value is a theoretically calculated value based on exposure and source table data.

Exposure data	<input type="checkbox"/> Target/Filter combination <input type="checkbox"/> kV value <input type="checkbox"/> Thickness of compressed breast <input type="checkbox"/> Focus (large or small) <input type="checkbox"/> Distance between focus and skin
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Source-table data	<input type="checkbox"/> Dose absorbed by the glandular for 50/50 % (glandular tissue/fatty tissue) <input type="checkbox"/> Transmission dose (mGy/mAs) <input type="checkbox"/> HVL values
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Users should be aware of that the dose value displayed is an estimated value and the accuracy of all parameters in the calculation affects the accuracy of displayed value.

Loading factor combination

The nominal X-ray tube voltage and the highest X-ray tube current available at that voltage: 40kV,125mA;

The highest X-ray tube current and the highest X-ray tube voltage available at that current: 160mA,31kV

The corresponding combination of X-ray tube voltage and X-ray tube current which results in the highest electric output power: 40kV,125mA

Nominal electric power: 4.8kW,Loading factor: 30kV,160mA,1s(160mAs)

The lowest current time products:2mAs(20kV、 100mA、 20ms)

The lowest resulting mAs of Automatic exposure control: 2mAs

Classifications

Protection against electrical shock	Class I, Type B, in accordance with IEC 60601-1 Attention: To avoid the risk of electrical shock, a protective conductor must be implemented when connecting this device to line power
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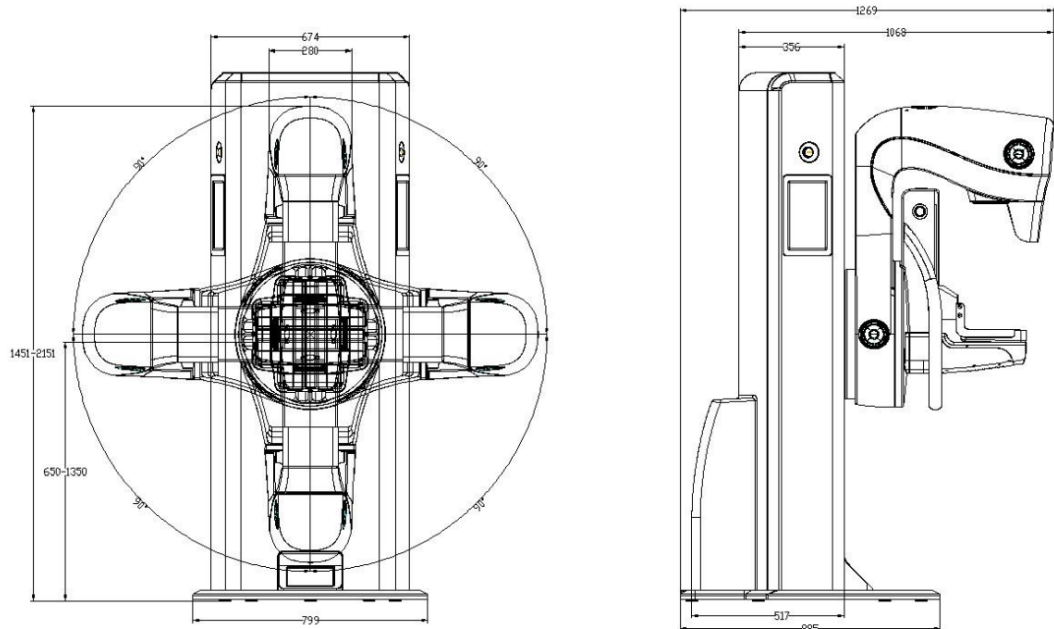
Degree of protection against ingress of water	Ordinary equipment (enclosed equipment without protection against ingress of water, protection class IPX0 (IEC60529)(Foot switch is class IP68)
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Degree of safety of application in the presence of flammable anesthetic mixture with air or nitrous oxygen	Not applicable not intended for flammable gases (APG)
Operating mode	Continuous operation with intermittent loading

Tomosynthesis

Scan angle range	$\pm 7.5^\circ$ 、 $\pm 20^\circ$
Exp. step	$\pm 7.5^\circ$: 1.5°/step $\pm 20^\circ$: 2.5°/step
Exp. Times	$\pm 7.5^\circ$: 11 times $\pm 20^\circ$: 17 times
Reconstruction slice thickness	1mm
Image time	$\pm 7.5^\circ$: 10s $\pm 20^\circ$: 20s

Stand

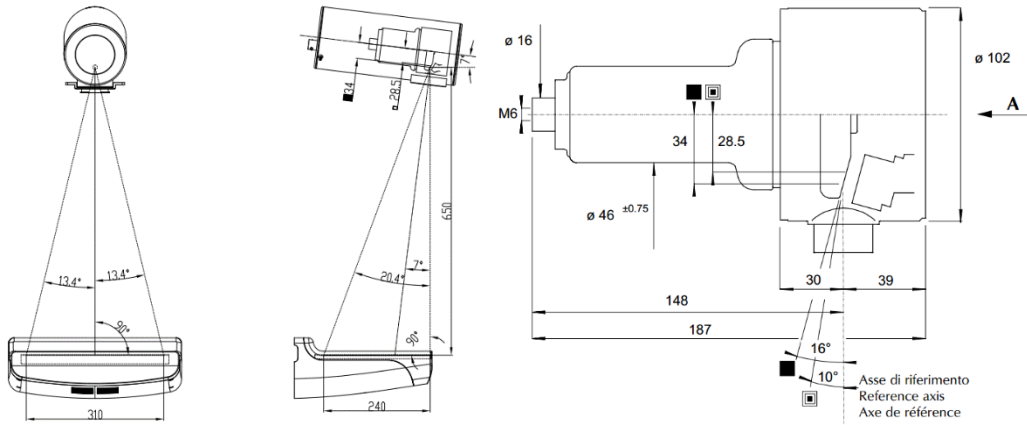


Stand size

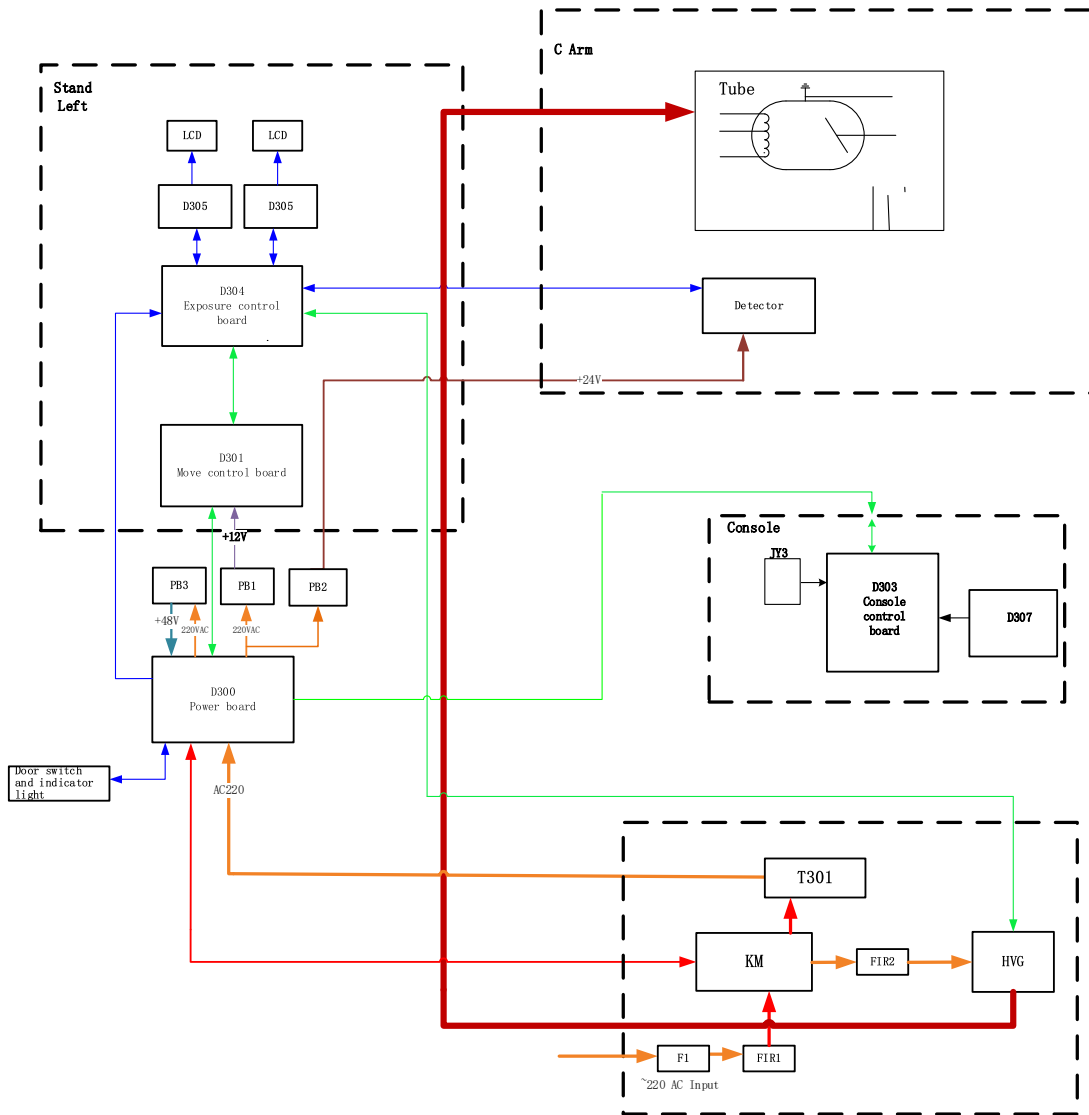
Vertical Travel	700mm
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Rotating Angle Range	-180°~180°
Focus-Image Distance (FID)	650mm
Weight	Max.400kg

Tube assembly



Electrical Connections



1.3.2 Environmental Condition

Transport & Storage Conditions

Temperature Range	-20°C - +55°C
Humidity Range	10% - 93%, no condensation
Atmospheric Pressure Range	50kPa - 106kPa

Operating Condition

Temperature Range	+10°C - +35°C
Humidity Range	30% - 75%, no condensation
Atmospheric Pressure Range	57kPa-106kPa

1.4 Electromagnetic Compatibility

Special EMC precautions must be obeyed during the use of medical electronic equipment and system installation and use must be conducted according to EMC information in the supplied file.

Potable or mobile RF communication equipment will influence medical electronic equipment.



Warning:

Other non-designated accessories, converters and cables are used.

The radiation may be increased or the anti-interference performance of the equipment or system may be degraded!

- ◆ Only the converter and cable which are used as internal subassembly spare parts and sold by the equipment or system manufacturers can be used.

The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should be assured that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - Guidance
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Conducted and radiated RF emissions CISPR 11	Group 1	The System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The System is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Conducted and radiated RF emissions CISPR 11	Class B	
Harmonic distortion IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker IEC 61000-3-3	Not applicable	



Caution:

The equipment or system is adjacent to or stacked with other equipment.

Normal operation can not be guaranteed!


- ◆ If the equipment or system must be adjacent to or stacked with other equipment, please pay attention to the operation conditions of the equipment or system.

The System is intended for use in the electromagnetic environment specified below. the customer or the user of the System should assure that it is used in such an environment			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic Discharge(ESD) IEC 61000-4-2	Contact ±8kV Air ±15 kV	Contact ±8kV Air ±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transients/bursts IEC 61000-4-4	±2 kV for input power port ±1 kV for signal input/output parts port 100 kHz repetition frequency	±2 kV for input power port ±1 kV for signal input/output parts port 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 610000-4-5	line-to-line ±0.5 kV, ±1 kV Line-to-ground ±0.5 kV, ±1 k, ±2 kV	line-to-line ±0.5 kV, ±1 kV Line-to-ground ±0.5 kV, ±1 k, ±2 kV	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Mains power quality should be that of a typical commercial or hospital Environment .If the user of the system requires continued operation during power mains interruptions, it is recommended that the SN-M Series Pump be power from an uninterruptible power supply or a battery
	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	
Voltage interruptions IEC 61000-4-11	0 % UT; 250/300 cycle	0 % UT; 250/300 cycle	
Rated power frequency magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level $U_T = 230V/50Hz$			

The System is intended for use in the electromagnetic environment specified below. The customer or user of the System should assure that it is used in used in such an environment.

IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment - guidance
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<p>Conducted disturbances induced by RF fields IEC 61000-4-6</p>	<p>3 V 0,15MHz–80MHz 6 V in ISM bands between 0,15MHz and 80 MHz 80 % AM at 1kHz</p>	<p>3 V 0,15MHz–80MHz 6 V in ISM bands between 0,15MHz and 80 MHz 80 % AM at 1kHz</p>	<p>Portable and mobile RF communications equipment Should be used no to any part of the SN-M Series Pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter Recommended separation distance</p> $d=1.2\sqrt{P}$
<p>Radiated RF EM Fields IEC 61000-4-3</p>	<p>3 V/m 80MHz to 2,7GHz 80% AM at 1kHz</p>	<p>3 V/m 80MHz to 2,7GHz 80% AM at 1kHz</p>	$d=1.2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d=2.3\sqrt{P} \quad 800 \text{ MHz to } 2,5\text{MHz}$ <p>Where P is the maximum output power rating of the transmitter in watts(w) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should Be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: </p>

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the System is used exceeds the applicable RF compliance level above, the System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the System.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V/m.

The System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2,5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

2. Product Use

2.1 Intended Use

The Navigator series system generates digital mammographic images that can be used for screening and diagnosis of breast cancer. The Navigator series system is intended for use in the same clinical applications as a 2D mammography system for screening mammograms. The Navigator series system can be used to generate 2D

digital mammograms and 3D mammograms. The screening examination may consist of: a 2D FFDM image set, a 2D and 3D image set, a synthesis 2D and 3D image set (the synthesis 2D image is generated from the 3D image set).

2.2 Patient Group

This system can be used to examine all kinds of patients (except for pregnant women). The use of this system needs to satisfy relevant requirements of the corresponding country/region.

Qualified medical staffs must decide whether it is suitable to conduct the X-ray examination on the patient according to the patient's health state and physical conditions.

2.3 Use Condition

This system is applicable to medical institutions such as hospital or clinic, etc.

Navigator series Digital breast tomosynthesis (hereinafter referred to as: Navigator DBT) can operate only in the environment approved or authorized by the manufacturer.

Requirements for climatic conditions stipulated in the chapter of **Technical Instructions** must be obeyed.

This system can not be used in MRI environment.

2.4 Contraindication

The mammography system has the following contraindicant requirements:

- inflammatory mass patients and pregnant/lactating patients.
- People who are pregnant, lactating or planning to become pregnant in the near future.
- Where the duration is less than 3 months since the last mammography examination.
- For the patient fit with implant after the breast cancer operation.

Note:

- ◆ It is necessary to tell the patient about the dangers and safety measures related to the examination. Before the examination, the doctor must confirm that the examination can be performed and ascertain whether it is necessary to adopt further preventive measures.
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2.5 User Information

Proper system use requires that the medical operator must be qualified and comply with applicable regulations of the country/region where he/she is located. In addition, the operators must be familiar with the operation manual and attach importance to the following parts:

- General Information
- Personal Safety
- Equipment Safety
- Maintenance

2.6 Training

Instruction in the use of the system can take place either through application training provided by a SINOMDT qualified application trainer or through self-training based on this Operator Manual.